DETAILED ACTION

1. Applicant's arguments in the reply filed on 5/4/2011 is acknowledged and entered into the record.

2. Accordingly, Claims 28, 29, 31, 32, 44-47 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 28-29, 31-32 and 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al (WO 94/09136, published 4/28/1994, cited on PTO-892 mailed 4/23/09) is maintained.

The reply filed 5/4/2011 again references the previously filed a Rule 131 Declaration (filed 10/23/2009 and 12/28/2009) with evidence showing that applicant tried to contact the non-signing inventor and informed the inventor that no response will constitute a refusal. The previously field Declaration under 37 CFR 1.131 filed on 10/23/09 and 12/28/2009 under 37 CFR 1.131 has been considered but still remain ineffective to overcome the applied reference because the Declaration is not

accompanied by a petition under 37 CFR 1.183 (see MPEP 409.03(d)). A petition under 37 CFR 1.183 requesting waiver of the signature of the unavailable inventor be submitted *WITH* the affidavit or declaration under 37 CFR 1.131.

To overcome the above deficiency, Applicant should resubmit the petition under 37 CFR 1.183 along with the evidence of refusal to sign provided in the most recent reply (filed 5/4/2011). In view of the absence of a "granted" petition, the rejection is maintained.

Thus, the rejection of claims 28-29, 31-32 and 44-47 under 35 U.S.C. 102(a) as being anticipated by Harris et al is maintained.

5. The rejection of claims 44-47 under 35 U.S.C. 102(b) as being anticipated by Adair et al (WO 91/09967, published 7/11/1991, cited on PTO-892 mailed 3/29/10) is maintained.

6. Adair et al teach a method of designing humanized heavy and light chain variable domain amino acid sequences of murine monoclonal antibody B72.3 comprising comparing the light and heavy chain variable domain sequences of B72.3 with the light and heavy chain sequences of two or more human antibodies (e.g., those in Kabat), wherein the human REI light chain frameworks are selected and the human EU heavy chain frameworks are selected for FR1, FR2 and FR3 and a human consensus heavy chain FR4 was selected and the selected human frameworks are incorporated with the corresponding light and heavy chain CDRs of B72.3 and the light chain mouse residue

at position 48 (2 amino acids from CDR2) and the heavy chain mouse residues at position 73, which is close to both CDRs 1 and 3 and could have a detrimental effect on antigen binding were retained in the humanized B72.3 antibody (i.e., residues predicted to have contacts with the CDRs and within a 4.5 Angstrom radius of any atoms within the CDRs). Adair et al also teach preparing the DNA sequences encoding the designed humanized B72.3 light and heavy chain variable domain amino acid sequences, operably incorporating the prepared humanized light and heavy chain variable domain sequences into expression vectors comprising the human light constant region and the human IgG1 constant region, transfecting host cells with the light and heavy chain vectors and culturing the cells under conditions to produce the humanized B72.3 antibody that binds mucin (see entire document, particularly Example 3 and pp. 10-15).

Thus, Adair et al anticipates the claims.

Response to Arguments

7. In the response filed 5/4/2011 applicants again argue that Adair et al. does not teach the limitation of selecting FR4 from a third human antibody. This argument has been carefully considered but not found to be persuasive. The broadest reasonable interpretation of the limitations of Claim 28 read on a method of designing amino acid sequences of variable domains of a humanized monoclonal antibody comprising selecting framework regions from a first, second, and third human antibodies, however the claim does not explicitly indicate the antibodies are different from each other. However, for the sake of the argument Adair et al. teach selecting FR4 from a

consensus sequence which would meet the limitations of being from an antibody other than the first and second antibodies. Applicant's state in their arguments (filed 5/4/2011) that a consensus sequences "is a way of representing the results of multiple sequence alignments". This teaching would indicate that the consensus sequences used to select FR4 was from several different antibodies, which again would meet the limitation recited in Claim 28. It is also noted that the claimed antibody is not distinguished structurally from the antibody of the prior art. For the reasons stated above, the rejection of record is therefore maintained.

Conclusion

8. Claims 28, 29, 31, 32, 44-47 are rejected.

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Friday, 9:00AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MN/

/LAURA B GODDARD/
Primary Examiner, Art Unit 1642